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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/073,881	05/06/1998	MAHENDRA S. RAO	T4903.CIP	1335

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/073,881

Applicant(s)

Rao et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 30, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15, 17, and 18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 17, and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/02 has been entered.
2. The amendment filed 12/30/02 has been entered.
3. The rejection of claims 9 & 16 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "dorsalizing agent" is withdrawn due to the cancellation of these claims.
4. The rejection of claims 1, 9-13, 15 and 16-18 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the cancellation of the claims, or because of Applicants' arguments. However, Applicants' comments on page 7 of the response necessitate a rejection under 35 U.S.C. 112, second paragraph, as indicated below.

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5. Applicant's arguments filed 12/30/02 have been fully considered but they are not deemed to be persuasive.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 15 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preambles of the claims recite "a method for generating mammalian neural crest stem cells". However, "inducing the NEP cells to differentiate" in step (c), as argued on page 7 of the response, alternatively results in differentiation of these neural crest stem cells, and therefore, no more generation of NEP cells, which is contradictory to that recited in the preamble; thereby, making the claims ambiguous.

8. Claims 1, 15 & 17-18 stand rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. (U.S. Patent 5,589,376), and by Anderson et al. (U.S. Patent 5,824,489), for the reasons made of record in Paper Nos: 11 (mailed 10/03/00) and 21 (mailed 7/8/02), and as follows.

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Applicants argue on pages 9-10 of the response that “[s]ince the Anderson patent[s] do not teach the steps for obtaining and harvesting neuroepithelial stem cells, the patents cannot anticipate the invention as now claimed”. In contrast to Applicants’ assertions, the instant claims themselves recite no step for “inducing the cells to generate neural crest stem cells”. In fact, the NEP cells are already present in Anderson’s tissue, similar to that as in steps (i), (ii) and (iii) of the claimed methods. Therefore, the Anderson patents teach all recited limitations of the claims.

In summary, both Anderson patents teach in their Examples 1-3 a method for obtaining neural crest stem cells derived from the neural tube from a mammalian/rat embryo (i.e., after closure of the neural tube), dissociating the cells, trypsinizing the cells, and plating the cells in culture medium comprising EGF, bFGF and NGF and chick embryo extract (CEE) (e.g., col. 12 of ‘376; col. 15 of ‘489) on fibronectin coated plates. Column 8, line 66- column 9 of ‘376 describes using fluorescence activated cell sorting (FACS) (i.e., antibody capture) using p75/LNGFR antibodies (i.e., as it relates to claims 17-18), as does column 10, line 34- column 11, and column 16, line 63- column 17 of ‘489.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

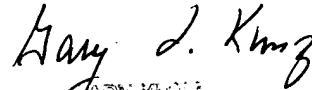
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
March 3, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNICAL CENTER 1240